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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,499	12/12/2003	Andrei W. Konradi	42837-20027.10	1891

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EXAMINER	
TUCKER, ZACHARY C	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,499	KONRADI ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 21Sep04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Requirement for Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5 and 6, (all in part), drawn to chemical compounds according to the molecular structure diagrams depicted therein, wherein the variable "Ar" is a carbocyclic aromatic ring system.

II. Claims 1, 2, 5 and 6 (all in part) and claims 3 and 4 (not in part) drawn to chemical compounds according to the molecular structure diagrams depicted therein, wherein the variable "Ar" is a heteroaromatic (*i.e.*, heterocyclic aromatic) ring system.

III. Claims 7-10 (all in part), drawn to methods of treating various inflammatory conditions, a method for binding VLA-4 in a biological sample and a pharmaceutical composition ostensibly for that purpose, wherein the compound according to any one of claims 1-6 is from Group I as set forth hereinabove.

IV. Claim7-10 (all in part), drawn to methods of treating various inflammatory conditions, a method for binding VLA-4 in a biological sample and a pharmaceutical composition ostensibly for that purpose, wherein the compound according to any one of claims 1-6 is from Group II as set forth hereinabove.

The inventions are independent or distinct, each from the other because:

Inventions I and III or II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case inflammatory conditions like those recited in instant claim 10 are treatable by a huge number of methodologies wherein drugs/compounds materially different from those of Group I or Group II are employed as the therapeutic agent.

Inventions I and II or III and IV or I and IV or II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are designed differently, in the case of the two Groups of different chemical compounds, which in turn will require different searches in the chemical literature. A reference rendering a compound from Group I as set forth hereinabove unpatentable will not necessarily render a compound from Group II as set forth hereinabove unpatentable. The methods in Groups III and IV are similarly unrelated, in that the therapeutic agent is a chemically different compound.

Lastly, the compounds in Group I are unrelated to the method in Group IV, and the compounds in Group II are unrelated to the method in Group III.

It is customary to give class/subclass designations when issuing a Requirement for Restriction. This has not been done in the case at hand because the claims cover so many different classes of compound. Upon receipt of a reply to this Requirement, a class/subclass designation will be determined, based on applicants' election of species for examination.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because

the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the Groups represent divergent subject mater and thus the inventions require a different field of search (see MPEP § 808.02) to determine patentability, restriction for examination purposes as indicated is proper.

This Requirement is Further Set Forth as Follows:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (a single chemical compound embraced by whichever Group is elected) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The search of the prior art will be begun based on what the identity of the elected species is.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, *and a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the

election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This Requirement is Subject to the Following Conditions:

The examiner has required restriction between compounds, pharmaceutical compositions, and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the patentable compound will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined pharmaceutical composition claims and method of use claims will be withdrawn, and the rejoined pharmaceutical composition and method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims, pharmaceutical composition claims and method of use claims may be maintained. Withdrawn pharmaceutical composition claims and method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the pharmaceutical composition claims and method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of an invention and a species of that invention to be examined even though the requirement be traversed (37 CFR 1.143).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Specification

The disclosure is objected to because of the following informalities:

There is no statement as to the continuity of the instant application at the first page of the specification. It is noted that the specification references the provisional applications upon which it is based, but no reference to the application which is the parent to the instant application is made, as required by 37 C.F.R. 1.78(a)(1)(iv)(i).

Appropriate correction is required.

Comment re Formula Numbering

The manner in which formula numbers are set out in the claims is inconsistent. For example, in claim 2, the preamble reads, "A compound of formula (2)," while a Roman numeral two represents the actual molecular structure diagram. In 4, the preamble specifies no particular formula number, while the formula is represented with a Roman

numeral one, the same number which represents the formula in claim 1. The compounds according to claims 1 and 4, however, are of a different scope.

Information Disclosure Statement

A signed and initialed PTO form 1449, which accompanied the Information Disclosure Statement filed 21 September 2004, is submitted herewith. Three of the cited references, the first two and last citations on page two of the PTO-1449 form, were not in the application file wrapper for the parent application. If applicant kindly supplies the missing references, the citations of which have been "lined through" on the PTO-1449 form, the examiner will consider them.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 5:45am to 2:15pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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